K021454
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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:
May 2, 2002

Submitter:
GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:
Joelle Neider
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (203) 949-8232
Fax: (414) 918-8113
Email: joelle.neider@med.ge.com

Device: Trade Name:
Unity Network ID

Common/Usual Name:
Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Classification Names: 21 CFR 870.2300

Classification for the externally connected devices are as follows:

Regulation Number	***Classification Name***	***Panel***	***Procode***
870.1110	Computer, blood pressure	Cardiovascular	74 DSK
870.1130	System, measurement, blood pressure, noninvasive	Cardiovascular	74 DXN
870.2300	Monitor, cardiac	Cardiovascular	74 DRT
876.1800	Urinometer	Gastro-urology	78 EXS
880.5725	Pump, infusion	General hospital	80 FRN
870.3535	System, balloon, intra-aortic and control	Cardiovascular	74 DSP
868.5895	Continuous ventilator	Anesthesiology	73 CBK
868.1730	Computer, oxygen uptake	Anesthesiology	73 BZL
870.2700	Oximeter	Cardiovascular	74 DQA
868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology	73 CCK
870.1915	Thermodilution probe	Cardiovascular	74 QGL
868.2375	Breathing Frequency Monitor	Anesthesiology	73 BZQ
868.2480	Monitor, Carbon Dioxide, Cutaneous	Anesthesiology	74 LKD

Predicate Devices:
Phillips Medical Systems, Inc., M2376A Device Link System – K012094

Device Description:

The Unity Network ID system communicates patient data from sources other than GE Medical Systems *Information Technologies* equipment to a clinical information system, central station, and/or GE Medical Systems *Information Technologies* patient monitors.

The Unity Network ID acquires digital data from eight serial ports, converts the data to Unity Network protocols, and transmits the data over the monitoring network to a Unity Network device such as a patient monitor, clinical information system or central station.

Intended Use:

Indicated for use in data collection and clinical information management through networks with independent bedside devices.

The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

Technology:

The Unity Network ID employs the same functional scientific technology as its predicate device.

Test Summary:

The Unity Network ID and its host patient monitoring system comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Unity Network ID:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the Unity Network ID is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

GE Medical Systems Information Technologies
c/o Ms. Joelle Neider
Regulatory Affairs Specialist
8200 W. Tower Ave.
Milwaukee, WI 53223

Re: K021454
Trade Name: Unity Network ID module
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 15, 2002
Received: August 16, 2002

Dear Ms. Neider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

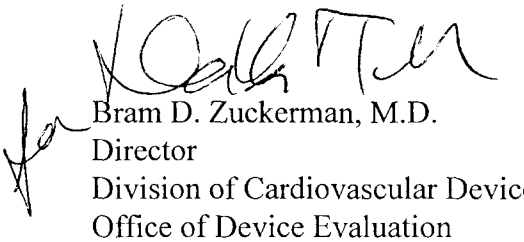
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown; 510(k) filed on May 2, 2002 K021454

Device Name: Unity Network ID

Indications for Use:

Indicated for use in data collection and clinical information management through networks with independent bedside devices.
The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021454